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Original Article

Clinical Efficacy of Bedaquiline-Containing Short-Course Regimens in Multi-Drug-Resistant Tuberculosis: Experience from Central Rajasthan

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Abstract

Background: Multidrug-resistant tuberculosis (MDR-TB) continues to pose a critical threat to global public health, with India bearing nearly one-fourth of the world's total burden. The emergence of bedaquiline-containing regimens has significantly improved treatment outcomes in MDR-TB due to enhanced bactericidal activity and shorter treatment duration.

Objectives: To evaluate the efficacy and treatment outcomes of a bedaquiline-containing short-course regimen in multidrug-resistant tuberculosis (MDR-TB) patients at a tertiary care center in Central Rajasthan.

Methods: This observational study was conducted among 100 MDR-TB patients registered at our center. Patients underwent detailed pre-treatment clinical, radiological, biochemical, and microbiological evaluation. Demographic details, co-morbidities, socioeconomic status, addiction history, and previous anti-tuberculosis treatment (ATT) exposure were recorded. We initiated patients on a short-course bedaquiline regimen and followed them according to the Programmatic Management of Drug-Resistant Tuberculosis (PMDT) guidelines. Treatment outcomes were categorized as cured, treatment completed, treatment failure, loss to follow-up, regimen change, or death. Sputum conversion, clinical improvement, radiological response, and adverse drug reactions were also assessed.

Results: Most patients (64%) were aged 21 to 50, the economically productive years, with a mean age of 34.97 ± 12.46 years. Males constituted 71% of the study population. Most patients were underweight (70%), and pulmonary tuberculosis was present in 92% of cases. Previous history of ATT was observed in 42% of patients. Smear conversion was achieved in 71% of patients, while radiological regression was noted in 62%. Complete clinical improvement occurred in 53% of cases. Final treatment analysis indicated a cure rate of 67%, with 11% died, 10% were lost to follow-up, 8% required regimen modification, and 4% experienced treatment failure. Adverse drug reactions were observed in 37% of patients, most commonly gastrointestinal symptoms and dermatological manifestations.

Conclusion: The bedaquiline-containing short course regimen demonstrated favorable treatment outcomes with acceptable safety among MDR-TB patients. Shorter treatment duration, improved cure rates, and manageable adverse effects support the wider implementation of bedaquiline-based regimens in the programmatic management of MDR-TB in India.

Keywords: Multidrug-resistant tuberculosis, MDR-TB, bedaquiline, short course regimen, treatment outcome, drug-resistant tuberculosis..

Introduction

Mycobacterium tuberculosis, since its early days, has been exacting a substantial toll of morbidity and mortality on humanity in the form of tuberculosis. India accounts for about one-fourth of the global burden of MDR-TB.[1] Over the past two decades, global mycobacterial drug resistance has worsened with the emergence and spread of multidrug-resistant (MDR-TB) and extensively drug-resistant tuberculosis (XDR-TB);

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Table 1: Showing demographic, microbiological status and other features of study participants

Variables	*Number Of Patients*
Age (in years)	
<20	10
20–50	64
>50	26
Gender	
Male	71
Female	29
BMI (kg/m^2)	
<18.5	70
>18.5	30
Sputum smears positive for AFB	26
CBNAAT – rifampicin resistance	95
Extrapulmonary TB	8
HIV seropositive	2
Previous history of ATT	42
Hypertension	19
Diabetes mellitus	17
Addiction	54
Complete clinical improvement	53
Sputum conversion	71
Radiological regression	62
Adverse drug reactions	37

MDR-TB strains are specifically defined by resistance to at least isoniazid and rifampicin.[2]

Bedaquiline represents a novel diarylquinoline drug class that targets mycobacterial ATP synthase, an essential enzyme for *Mycobacterium tuberculosis (MTB)* energy production. Pre-clinical, laboratory, and animal models demonstrate its potent bactericidal and sterilizing activities against MTB. Pharmacokinetically, the drug features a high volume of distribution, extensive tissue penetration, high plasma protein binding, and hepatic metabolism. Due to an extended half-life, terminal elimination continues for up to 5.5 months after treatment cessation.[3] In June 2013, the WHO first recommended bedaquiline for treating specific forms of rifampicin-resistant and multidrug-resistant tuberculosis (RR/MDR-TB) in adults.[4]

Methods

This study was done among the MDR-TB patients registered at our center. We selected 100 patients after a comprehensive pre-treatment assessment as per national guidelines, which included physical, radiological, and biochemical evaluations, as well as collecting data on their treatment history, co-morbidities, educational and occupational background, addiction, and socioeconomic status through interviews.

After the pre-treatment evaluation, patients began their designated short course regimen. We defined primary outcomes based on PMDT guidelines, categorizing them into cured, treatment completed, loss to follow-up, regimen change, treatment failure, or deceased. Patients who finished treatment but were still awaiting culture results were classified as "treatment complete." We also assessed sputum conversion rates and clinical/radiological improvements to evaluate final outcomes. Adverse drug reactions were also documented and categorized.

All data from the pre-treatment evaluation and follow-up were meticulously recorded in structured forms and entered into Excel for analysis. Following data verification, we performed a descriptive analysis and calculated measures of association based on variable types. Access to patient data was granted by the program manager and the designated Nodal TB officer through both registers and the Nikshay portal. Verbal consent was obtained from both the patients and their caregivers for follow-up purposes.

Results

In this study, a substantial portion of patients (64%) fell within the economically productive age group of 21 to 50 years, with a mean age of 34.97 ± 12.46 years and a median age of 45 years; the age range was 13 to 79 years. The male-to-female ratio was 2.4:1, reflecting a higher prevalence of male patients. The most common occupation was manual labor (30%), followed by farmers (17%), drivers (4%), housewives (17%), business owners (15%), students (11%), and other professionals (6%). Socioeconomic status was predominantly lower, with 26.92% of patients classified as lower and 28.46% as upper lower. Treatment outcomes revealed that 53% of patients experienced complete improvement, 22% had partial improvement, and 10% showed no improvement.

Table 1 outlines the demographic, clinical, radiological, and microbiological characteristics of the study population. 70% of patients were underweight, while 28% had a normal weight and only 2% were overweight. There were 92% of patients diagnosed with pulmonary tuberculosis (PTB), while 8% had extrapulmonary tuberculosis (EPTB). Within the EPTB group, four patients presented with cold abscesses, one with cervical lymphadenitis, two with pleural tuberculosis, and one with ascites. 65% of patients had a history of previous TB treatment, whereas 35% were newly diagnosed with drug-resistant (DR) strains.

At treatment initiation, on chest radiography, 5 patients had minimal disease, 48 had moderately advanced disease, and 34 had far advanced disease. By the end of treatment, the distribution changed to 11 patients with minimal disease, 16 with moderately advanced disease, and 35 with far advanced disease. Additionally, 17 patients exhibited radiological progression, while 62 showed radiological regression (Figure 1).

Out of 100 patients,67% were cured, 11% died, 4% showed treatment failure, 10% had lost to follow-up and in 8% the regimen was changed due to the development of adverse

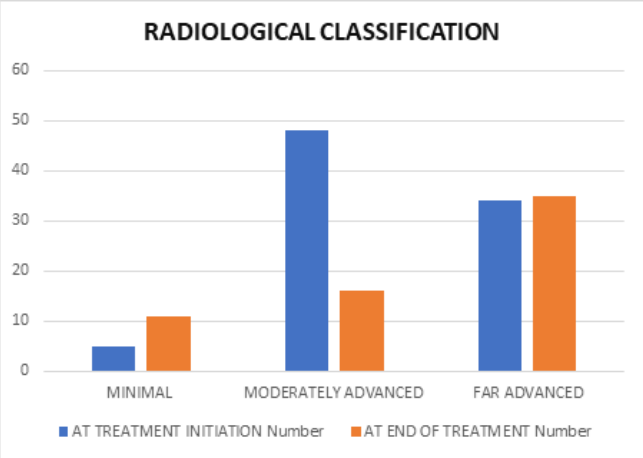

Figure 1: Radiological classification of disease extent among study patients

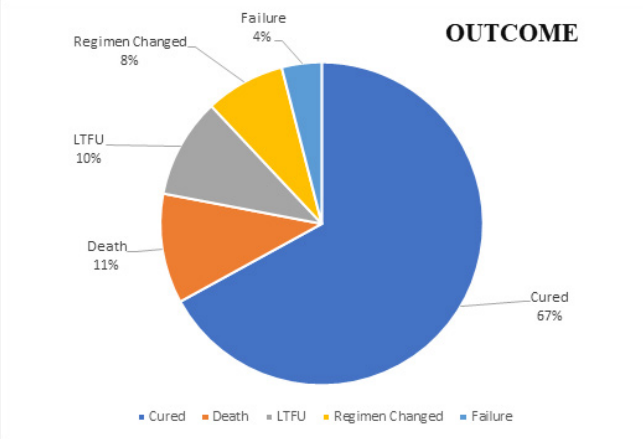

Figure 2: Showing distribution of study cases according to treatment outcome

effects or resistance to other drugs (Figure 2). The outcomes among EPTB included seven patients cured and one lost to follow-up.

Patients in this study experienced a range of adverse drug reactions (ADRs), including nine cases of gastrointestinal symptoms, five of peripheral neuropathy, three instances of hepatotoxicity, ten cases of dermatologic issues, three cases of psychiatric symptoms, five instances of joint pain, and one case each of anemia and hypothyroidism. QTC prolongation was seen in only two patients and does not required change in the drug regimen.

Discussion

A majority of the cohort (64%) consisted of economically productive individuals aged 21 to 50 years (mean age: 34.97 years), with a notable male predominance. 70% of patients were underweight, while 28% had a normal weight and only 2% were overweight, indicating a higher prevalence of the disease among those with low body mass index (BMI). A significant portion of the cohort, 65%, had a history of previous TB treatment, whereas 35% were newly diagnosed with drug-resistant (DR) strains. Among the previously treated patients, there were five reported deaths, while six deaths and three treatment failures occurred among the newly diagnosed cases. Seung *et al.*[5] found multidrug-resistant TB (MDR-TB) in 3.8% of new patients and 20% of previously treated patients.

Clinically, by the end of the treatment regimen, 53 patients showed complete improvement, 22 demonstrated partial improvement, and 10 had no symptom improvement. The smear conversion rate was 80.68%, comparable to a 2023 study by Mary Prince R *et al.*[6] that reported 84.4% culture conversion by three months and 93.1% by six months for patients on a bedaquiline-containing short course regimen.

Overall, in this study, 67% of patients were cured, 11% died, 4% experienced treatment failure, 10% were lost to follow-up, and 8% had their regimen changed. This is in line with findings from a 2023 study by UR Rehman O[7], which indicated a treatment success rate of 76.9% across 36 pooled observational studies. Among these studies, treatment failure rates averaged 4.7%, while death rates pooled at 8.9%. A systematic review and meta-analysis by Fekadu G. *et al*[8] from 2012 to 2024 observed a treatment success rate of 83%, mortality of 5% and treatment failure with lost to follow-up in 4% each. Another systematic review and meta-analysis by Hatami H. *et al.*[9] among 3976 patients found a treatment success rate 74% in 24 observational studies and 86% in 4 experimental studies. Mbuagbaw L. *et al.*[10] observed sputum conversion in 78%, treatment success rate in 65%, with more unfavorable outcomes among elderly, HIV seropositive, those with cavitation and more severe resistance profile. A single arm meta-analysis by Zhou Y *et al.*[11] among 8166 patients from 11 studies observed pooled treatment success rate in 78% patients. A similar Indian study from south-eastern Rajasthan[6] observed favorable treatment outcome in 83%, death in 6% and treatment failure in 3%. The overall analysis of literature reflects that bedaquiline containing shorter regimens are effective and safer for managing MRD-TB across different settings.

Among the range of adverse drug reactions (ADRs), dermatologic issues (10%) and gastrointestinal symptoms (9%) were commonly seen followed by peripheral neuropathy (5%), joint pain (5%), hepatotoxicity (3%), psychiatric symptoms (3%), QTC prolongation (2%) and anaemia and hypothyroidism (1% each). Other studies have also found such adverse events in different proportions but not severe enough to discontinue/modify treatment regimen in majority of the patients[8].

In conclusion, the WHO endorses bedaquiline for standard MDR-TB treatment. Incorporating bedaquiline into this short-course regimen advances drug-resistant TB management by enhancing efficacy and patient adherence. Reducing

treatment duration to approximately six months down from the traditional 18 to 24 months enhances patient compliance and mitigates resource constraints within healthcare systems.

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